REMARKS

Claims 1-6, 8-19, and 21-26 are now pending in the above-captioned application.

REJECTION UNDER 35 U.S.C. §101, First Paragraph

Claims 14-25 were rejected under 35 U.S.C. §101, as being directed toward non-statutory subject matter. The Examiner argues that the method claims 14-25 do not define a **tangible result** that qualifies as Patentable Subject Matter under 35 USC§101.

Much ink has been spilled recently on the nature of §101 rejections. The Federal Circuit, in *State Street Bank*, indicated that in certain circumstances, methods of doing business may be patentable. The result has been a flood of Patent Applications at the United States Patent Office, many of which are directed toward somewhat questionable methods, which may or may not qualify as statutory subject matter under 35 USC §101.

In response to this flood of applications, the Patent Office has issued a set of interim guidelines for Examination of applications which appear to be related to "non traditional" subject matter. See, e.g., http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf.

Applying these guidelines to the present invention, it is clear that the present invention is useful and novel, and **tangible** as defined in the USPTO's own guidelines and the case law, and thus qualifies as statutory subject matter under 35 USC §101. The USPTO *Guidelines* recite:

> The claimed invention as a whole must be **useful and accomplish a practical application**. That is, it must produce a **"useful, concrete and tangible result."** *State Street*, 149 F.3d at 1373-74, 47 USPQ2d at 1601-02. **The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research** (*Brenner v. Manson*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96 (1966)); *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); *In re Ziegler*, 992 F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). The applicant is in the best position to explain why an invention is believed useful. Accordingly, a complete disclosure should contain some indication of the practical

> application for the claimed invention, i.e., why the applicant believes the claimed invention is useful. Such a statement will usually explain the purpose of the invention or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful. See MPEP § 2107 for utility examination guidelines. An applicant may assert more than one utility and practical application, but only one is necessary. (emphasis added)

The present invention is clearly useful, as anyone who has visited any doctor's office will testify. Despite incredible advances in computerization of records in almost every area, including government (as evidenced by the Patent Office, for example), medical science remains stubbornly in the 1960's. Many medical practices still maintain patient files on paper, with the associated massive filing rooms and clerical workers. This antiquated system of record-keeping results in data being lost or misplaced, and a patient being forced to recount their medical history, from memory, whenever contacting a new doctor or medical professional. Paper records can also result in misdiagnosis, medication conflicts, and problems in patient billing.

Thus it is clear the present invention is "useful" and in fact is desperately needed. However, what exactly are the requirements of "tangible result"? Again, the Patent Office guidelines list a set of criteria for evaluating this aspect of 35 USC§101:

> **Practical Application That Produces a Useful, Concrete, and Tangible Result**
>
> For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." *AT&T,* 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the §101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. §101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. In determining whether a claim provides a practical application that produces a useful, tangible, and

concrete result, the examiner should consider and weigh the following factors:

(1) "USEFUL RESULT"

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP §2107 and *Fisher*, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of "specific" and "substantial"). In addition, when the examiner has reason to believe that the claim is not for a practical application that produces a **useful result**, the claim should be rejected, thus requiring the applicant to distinguish the claim from the three §101 judicial exceptions to patentable subject matter by specifically reciting in the claim the practical application. In such cases, statements in the specification describing a practical application may not be sufficient to satisfy the requirements for section 101 with respect to the claimed invention.

Likewise, a claim that can be read so broadly as to include statutory and nonstatutory subject matter must be amended to limit the claim to a practical application. In other words, if the specification discloses a practical application of a §101 judicial exception, but the claim is broader than the disclosure such that it does not require a practical application, then the claim must be rejected. (emphasis added)

As noted above, the present invention clearly provides a "useful result" and thus meets this aspect of 35 USC §101.

(2) "TANGIBLE RESULT"

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a §101 judicial exception, in that the process claim must set forth **a practical application of that §101 judicial exception to produce a real-world result.** *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also *Corning*, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract." (emphasis added)

Many Examiners misinterpret the "tangible result" requirement to mean that the device must act

on some physical mechanism (a gear, lever, or computer apparatus, for example) in order to be "tangible". However, as the USPTO *Guidelines* make clear, the term :tangible means only that it produce a "real world" result. In the present invention, as claimed, a patient record is produced. A Patient record is a tangible thing, whether in printed or electronic form. Thus, it is clear a tangible result is produced here.

> (3) "CONCRETE RESULT"
> Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. *In re Swartz*, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether that process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary artisan in that field. An appropriate rejection under 35 U.S.C. §101 should be accompanied by a lack of enablement rejection under 35 U.S.C. §112, paragraph 1, where the invention cannot operate as intended without undue experimentation. See infra.

The "concrete result" requirement is also misinterpreted by many Examiners to literally mean something made in concrete (e.g., physical form) when in fact, the requirement means that the process is reproducible. It is clear from the present Specification that the method of the present invention is clearly reproducible.

Creating patient records and maintaining them in such a manner that they are accessible to Patient and Doctor alike is not a trivial matter or a theoretical algorithm with no real-world applications. On the contrary, the method of the present invention solves very pressing real-world problems. The end product, a customized patient report, with health risk assessment scores, disease tracks, and medication compliance monitoring, are all concrete and tangible elements, not merely abstract thoughts or ideas. The claimed subject matter in *State Street Bank* comprised an investment score for evaluating securities. If the Federal Circuit and Supreme court find such a score patentable under 35 USC §101, then surely a patient risk score or health summary record is similarly patentable.

The rejection under 35 USC§101 is not supported by the law, or even under the USPTO's own *Guidelines* in applying that law. As such, the rejection should be withdrawn.

REJECTION UNDER 35 U.S.C. §102

Claims 1-26 were rejected under 35 U.S.C. §102(e) as being anticipated by Joao U.S. Patent No. 6,283,761. Applicant respectfully traverses this rejection.

In order to be complete, an anticipation-type rejection must contain two elements:

1. The reference must qualify as "Prior Art" under one of the sections of 35 U.S.C. §102; and
2. The reference must explicitly teach *ALL* of the features of the claimed invention.

Joao has an effective date prior to applicant's filing date, but less than one year prior to applicant's filing date. Thus, the reference qualifies under 35 USC §102(e). Applicant has not explored whether it is possible to "swear behind" this reference at the present time, as it does not appear that the reference truly teaches or suggests all of the claimed features of the present invention.

The Joao patent describes a series of applications for a collection of information concerning the health of a patient. It also describes a group of sources for the information many of which are referenced in the present application.

However, what is not described or considered by Joao is the unique method of acquiring and processing the information to create a format that is understandable to a patient and simultaneously useful to the physician. The Joao method has failed in practice for this reason and will continue to fail.

The unique method of the present invention uses internationally recognized codes that are used every day by the physicians and other providers of health care to report all their transactions that result in payments. Since every healthcare provider uses these codes there is no need for a physicians to alter their daily practices for reporting purposes and no additional coding is required as is required by the Joao system. The system of the present invention then processes these codes creating the unique **health**

summary record, which makes the information simultaneously useful to all parties including the patients.

The system of the present invention uses the ICD and other codes to automatically create the unique health summary record. This is one of the unique features of the present invention, which makes the system function and is not considered in the Joao application.

In the present invention, the health summary record described is created by truncating and sorting the standard codes. The unique health summary record is based on rules that are used to create the permanent and temporary problem lists; surgical diagnoses; encounters; and the like, as described in the present application. The creation of this unique summary allows targeted health information to be directed to the patients and physicians either directly or through links to the WEB. This feature is not addressed in the Loao Patent. Some links are specific to the needs of the patients while others meet the needs of the physicians. The links are identified by the codes and can be to nationally recognized government sites or created specifically by my system.

Thus, the Joao patent does not describe the health summary record nor does it describe any practical method of turning a huge collection of randomly acquired data into useful information. There is an old saying that "information beats data." The system describes in the present application addresses this issue. The links further encourage the patients as well as the physicians to use the system, which does not interfere with their current relationships. The additional uses of this type of information are outlined in the current application.

The claims have been amended to more clearly point out these features of the present invention. Independent claims 1 and 14 recite the creation of health summary records from patient interview and patient encounter information (e.g., office visit). From these HSRs, a number of unique reports may be generated, for patients, attending physicians, or insurance companies. Each report may be tailored to the needs of each recipient.

Note that in the Office Action, the limitations of many of the dependent claims were not addressed at all. Applicant submits that these dependent features are separately patentable and should be addressed on their merits.

Thus, for example, in claims 1 and 14, the health summary record may be used to create a medical report for an attending physician, including a health risk score (claims 2, 15), disease management track (claims 3, 16), medication recommendation (claims 4, 17), and treatment recommendation (claims 5, 18). A patient report may also be generated (claims 6, 19) including patient education information (e.g., links to disease related data, or educational information itself). The features of the dependent claims were not addressed in the Office Action rejection, because Joao does not teach or suggest such features. Joao teaches only accumulating data and perhaps making a diagnosis.

Claims 7 and 20 were cancelled, as they were deemed redundant in view of the amendments to the previous claims.

Claims 8 and 21 recite the limitations of generating patient medication non-compliance reports, which indicate to a physician whether or not a patient has indeed filled their prescription. This limitation was not addressed in the Office Action and is neither taught nor suggested by Joao. The generation of a medication non-compliance report is important, as it allows the physician to follow-up on treatment progress and remind the patient if medications are not being taken properly.

Claims 9 and 22 include the limitations of creating entries for temporary and permanent medical conditions. Again, this limitation was not addressed in the Office Action nor is it taught or suggested by Joao. The use of temporary and permanent classifications allows for classifying medical history elements based upon their usefulness in the long term to a patient and physician. Permanent conditions can be stored in the medical history for long term use, whereas temporary conditions might be deleted after a predetermined time period if not deemed important. In the Prior Art, all medical history elements

are treated equally, resulting in a large amount of data to be stored, much of which may be irrelevant to a physician for future use.

Claims 10 and 23 were cancelled, as they were deemed redundant in view of the amendments to the previous claims.

Claims 11 and 24 recite the customized medical reports include doctor reports summarizing patient medical history and medical condition. Again, Joao does not teach or suggest making a customized report for different types of users.

Claims 12 and 25 recite that the customized medical reports include medical provider reports summarizing patient medical claim history and medical claim status. Again, Joao does not teach or suggest making a customized report for different types of users.

Claims 13 and 26 recite the limitations of downloading medical reports to a PDS and then uploading data using the PDA to update a health summary record. While the use of a PDA in the medical field may be known, applicant's compressed health summary record is unique.

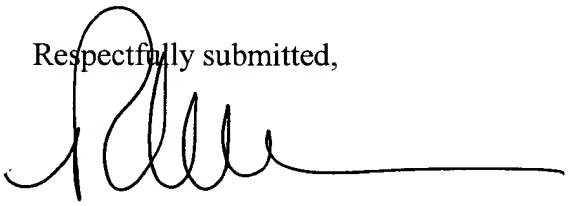
CONCLUSION

The subject matter of the present application is clearly statutory subject matter as defined under 35 USC 101. The Joao reference only broadly teaches storing medical data, and does not disclose the limitations of creating compressed health summary records or generating customized reports from the health summary records. Joao does not teach any of the claimed limitations of the dependent claims which were not expressly addressed in the Office Action.

The claims have been amended to more clearly distinguish the present invention from Joao. Redundent claims have been cancelled. As such, all of claims 1-6, 8-9, 11-19, 21-22, and 24-26 are now in condition for allowance.

An early Notice of Allowance is respectfully requested.

Respectfully submitted,



Robert P. Bell
Registration Number 34,546

Robert Platt Bell
Registered Patent Attorney
P.O. Box 310
Aurora, New York 13026

(703) 474-0757

June 12, 2006